DEPARTMENT OF ENERGY

Economic Regulatory Administration

10 CFR Part 507

[Docket No. ERA-R-78-19E]

Powerplant and Industrial Fuel Use Act of 1978; Deferral of Reports Required Under 10 CFR Part 507

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Deferral of Deadline for Filing Certain Reports.

SUMMARY: On May 8, 1979, the Economic Regulatory Administration (ERA) of the Department of Energy issued interim rules which would exclude certain fuels from the terms "natural gas" and "petroleum" for purposes of the Powerplant and Industrial Fuel Use Act. (Part 507, Fuel Classification and Reporting Requirement; 44 FR 29016, May 17, 1979). Incorporated in Part 507 are several reporting requirements due January 30 and 31, 1980, relating to natural gas and petroleum which are considered to be commercially unmarketable (§§ 507.6 and 507.7) and natural gas produced from small wells and used by powerplants (§ 507.5).

We believe that it would be in the public interest to defer filing the reports pursuant to 10 CFR Parts 507.5, 507.6 and 507.7 for such time as is necessary to gain experience in implementing the remaining provisions of Part 507. Such reports will be deferred until further notice is published in the Federal Register.

DATES: The January 30 and 31, 1980 deadlines for filing the appropriate reports pursuant to Part 507 are deferred until further notice.

FOR FURTHER INFORMATION CONTACT: John Dean (Office of Fuels Conversion), Economic Regulatory Administration, Department of Energy, 2000 M Street, NW., Room 3322-H, Washington, D.C. 20461 (202) 634-6526.

Issued in Washington, D.C. January 19, 1980

F. Scott Bush,

Assistant Administrator, Regulations and Emergency Planning, Economic Regulatory Administration.

[FR Doc. 80-2427 Filed 1-24-80; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 182, 184 and 186

[Docket No. 78N-0013]

Sulfuric Acid and Ammonium, Calcium, Potassium, and Sodium Sulfates; Affirmation of Gras Status

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that sulfuric acid and ammonium, calcium, and potassium sulfates are generally recognized as safe (GRAS) as direct human food ingredients. The agency also affirms that sodium sulfate is GRAS as an indirect human food ingredient. The safety of these ingredients has been evaluated under the agency's comprehensive safety review.

EFFECTIVE DATE: February 25, 1980.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 28, 1978 (43 FR 12874), FDA proposed to affirm that sulfuric acid and ammonium, calcium, potassium, and sodium sulfates are GRAS when used as direct and/or indirect human food ingredients. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on sulfates, a mutagenic evaluation report on potassium sulfate, which was not available at the time the proposal was published, and the report of the Select Committee on GRAS Substances (the Select Committee) have been made available for public review in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

In addition to proposing the above actions, the FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for sulfuric acid and ammonium, calcium, potassium, and sodium sulfates for other than the proposed conditions of use. Persons asserting additional or extended uses, in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of the sanction so that the safety of any prior-sanctioned uses could be determined at this time. That notice was also an opportunity to have prior-sanctioned uses of sulfuric acid and ammonium, calcium, potassium, and sodium sulfates approved by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), if the prior-sanctioned use could be affirmed as safe on the basis of information and data now available to FDA. Notice was also given that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert the sanction at any future time.

No reports of prior-sanctioned uses for sulfuric acid and ammonium, calcium, potassium, and sodium sulfates were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of sulfuric acid or ammonium, calcium, potassium, and sodium sulfates under conditions different from those set forth in this regulation has been waived.

One comment was submitted in response to the FDA proposal on sulfuric acid and ammonium, calcium, potassium, and sodium sulfates. The comment requested that sodium sulfate be listed under Part 184 as a GRAS substance for direct food use on the grounds that its toxicity is similar to the toxicity of sodium chloride, and it is currently used in the manufacture of starch and in caramel production. To support GRAS status further, the comment stated that sodium sulfate also occurs naturally in foods. The comment more specifically requested GRAS affirmation for sodium sulfate as a processing aid in the chemical modification of food starch by propylene oxide. Sodium sulfate is used to inhibit swelling of the starch granules during chemical modification and is allegedly the safest, most effective, and most economical agent for this purpose. The comment was concerned that if this use of sodium sulfate does not receive GRAS affirmation, then any residual sodium sulfate remaining in food starch after chemical modification would be an unapproved food additive.

FDA agrees with the comment that, because direct food uses of sodium sulfate were not addressed in the proposal, the regulatory status of sodium sulfate as a processing aid in starch modification needs to be clarified. An existing FDA food additive regulation (§ 172.892 (21 CFR 172.892)) deals with a starch modification process employing phosphorus oxychloride, propylene,

propylene oxide, and sodium sulfate. That process (§ 172.892(f)) involves the use of sodium sulfate at levels up to 5 percent, followed by thorough washing of the modified starch product to remove residues of sodium sulfate and other reaction ingredients. At the time FDA approved the propylene oxide-phosphorus oxychloride procedure, it considered the use of sodium sulfate in that procedure to be GRAS and thus not a food additive use. Sodium sulfate was not listed specifically in § 172.892(e) because, at the time that regulation was published, FDA policy was to list only food additives in food additive regulations, not substances whose use was considered to be GRAS. FDA still considers sodium sulfate, when used in the chemical modification of food starch by propylene oxide authorized in § 172.892(f), to be GRAS and, thus, not a food additive. Rather than formally list this restricted direct food use of sodium sulfate in the GRAS regulations at this time, the agency plans to cover this and other unlisted direct food uses of sodium sulfate in the forthcoming cyclic review of direct food additives.

In its original proposal, FDA proposed to establish food-grade specifications for the indirect use of sodium sulfate. Since then, however, the agency has reconsidered the necessity for imposing food-grade specifications on indirect GRAS substances, such as sodium sulfate. The agency has concluded that, as a general rule, food-grade specifications are not necessary to ensure the safety of an indirect GRAS substance, provided the substance is of a purity suitable for its intended use in accordance with § 170.30(h)(1). This conclusion is based on the fact that indirect uses generally result in extremely low levels of consumer exposure to the additive and correspondingly low levels of exposure to any impurities that may be present. If food-grade specifications are found necessary in a particular case to ensure the safety of an indirect GRAS ingredient, the agency will include them in the regulation. In the case of sodium sulfate, FDA concludes that specifications are not necessary. Therefore, the final regulation governing the use of sodium sulfate as an indirect GRAS ingredient has been modified in proposed § 186.1797(b) by removing the specifications. The agency intends to publish a proposal in the near future to amend its procedural regulations in Part 186 to reflect this new policy regarding specifications for indirect GRAS substances.

Consistent with its traditional practice, FDA proposed originally to establish separate regulations for sulfuric acid and calcium sulfate in Parts 184 and 186 to govern their direct and indirect GRAS uses, respectively. Under § 184.1(a), however, ingredients affirmed as GRAS for direct food use in Part 184 are considered to be GRAS for indirect uses without there being a separate listing in Part 186. In light of § 184.1(a), FDA has reconsidered its traditional practice of establishing separate listings in Part 186 for substances it affirms as GRAS for direct use in Part 184 and has concluded that the duplicative listing in Part 186 is unnecessary, as a general rule, and may cause confusion. Thus, unless it is necessary based on safety considerations to impose specific purity specifications or other restrictions on the indirect use of a GRAS substance, FDA will no longer list in Part 186 substances that are affirmed as GRAS for direct use in Part 184. In keeping with this change in policy, FDA will not promulgate § 186.1095 and 186.1230 as originally proposed. The indirect uses of sulfuric acid and calcium sulfate proposed for inclusion in §§ 186.1095 and 186.1230 are authorized under §§ 184.1095 and 184.1230, respectively, and § 184.1(a).

The agency also has determined that an indirect substance whose GRAS status for indirect use is based on its affirmation as GRAS in Part 184 need not comply, as a general rule, with the purity specifications made applicable to the direct use of the substance in the Part 184 regulation, as long as it is of a purity suitable for its intended indirect use in accordance with § 170.30(h)(1). This conclusion is based on the fact that indirect uses generally result in extremely low levels of consumer exposure to the additive and correspondingly low levels of exposure to any impurities that may be present. As noted in the preceding paragraph, however, if specific purity specifications for the indirect use of a GRAS substance are necessary based on safety considerations, a regulation establishing such specifications will be promulgated in Part 186. In the case of sulfuric acid and calcium sulfate, no specific purity specifications are necessary for their indirect use.

Although the policies discussed in the two preceding paragraphs are not inconsistent with FDA's current regulations, FDA will publish a proposal in the near future to amend its procedural regulations in Parts 184 and 186 to reflect clearly the current policies.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 182, 184, and 186 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by deleting the entry for "Sodium sulfate."

§ 182.90 [Amended]

b. In § 182.90 *Substances migrating to food from paper and paperboard products* by deleting the entries for "Calcium sulfate," "Sodium sulfate," and "Sulfuric acid."

§§ 182.1095, 182.1143, 182.1643, and 182.5230 [Deleted]

c. By deleting § 182.1095 *Sulfuric acid,* § 182.1143 *Ammonium sulfate,* § 182.1643 *Potassium sulfate,* and § 182.5230 *Calcium sulfate.*

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. Part 184 is amended by adding new §§ 184.1095, 184.1143, 184.1230, and 184.1643, to read as follows:

§ 184.1095 Sulfuric acid.

(a) Sulfuric acid (H_2SO_4, CAS Reg. No. 7664–93–9), also known as oil of vitriol, is a clear, colorless, oily liquid. It is prepared by reacting sulfur dioxide (SO_2) with oxygen and mixing the resultant sulfur trioxide (SO_3) with water, or by reacting nitric oxide (NO) with sulfur dioxide and water.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972),[1] which is incorporated by reference.

(c) The ingredient is used as a pH control agent as defined in § 170.3(o)(23) of this chapter and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.014 percent for alcoholic beverages as defined in § 170.3(n)(2) of this chapter and 0.0003 percent for cheeses as defined in § 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in

[1] Copies may be obtained from: National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20037.

this section do not exist or have been waived.

§ 184.1143 Ammonium sulfate.

(a) Ammonium sulfate ($(NH_4)_2SO_4$, CAS Reg. No. 7783–20–2) occurs naturally and consists of colorless or white, odorless crystals or granules. It is prepared by the neutralization of sulfuric acid and with ammonium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d. Ed. (1972) as amended by the first supplement (1974),[1] which are incorporated by reference.

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, and processing aid as defined in § 170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.15 percent for baked goods as defined in § 170.3(n)(1) of this chapter and 0.1 percent for gelatins and puddings as defined in § 170.1(n)(22) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1230 Calcium sulfate.

(a) Calcium sulfate ($CaSO_4$, CAS Reg. No. 778–18–9 or $CaSO_4 \cdot 2H_2O$, CAS Reg. No. 10101–41–4), also known as plaster of Paris, anhydrite, and gypsum, occurs naturally and exists as a fine, white to slightly yellow-white odorless powder. The anhydrous form is prepared by complete dehydration of gypsum, below 300° C, in an electric oven.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972) as amended by the first supplement (1974),[1] which are incorporated by reference.

(c) The ingredient is used as an anticaking agent as defined in § 170.3(o)(1) of this chapter, color and coloring adjunct as defined in § 170.3(o)(4) of this chapter, dough strengthener as defined in § 170.3(o)(6) of this chapter, drying agent as defined in § 170.3(o)(7) of this chapter, firming agent as defined in § 170.3(o)(10) of this chapter, flour treating agent as defined in § 170.3(o)(13) of this chapter, formulation aid as defined in § 170.3(o)(14) of this chapter, leavening agent as defined in § 170.3(o)(17) of this chapter, nutrient supplement as defined in § 170.3(o)(20) of this chapter, pH control agent as defined in § 170.3(o)(23) of this chapter, processing aid as defined in § 170.3(o)(24) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, synergist as defined in § 170.3(o)(31) of this chapter, and texturizer as defined in § 170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 1.3 percent for baked goods as defined in § 170.3(n)(1) of this chapter, 3.0 percent for confections and frostings as defined in § 170.3(n)(9) of this chapter, 0.5 percent for frozen dairy desserts and mixes as defined in § 170.3(n)(20) of this chapter, 0.4 percent for gelatins and puddings as defined in § 170.3(n)(22) of this chapter, 0.5 percent for grain products and pastas as defined in § 170.3(n)(23) of this chapter, 0.35 percent for processed vegetables as defined in § 170.3(n)(36) of this chapter, and 0.07 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1643 Potassium sulfate.

(a) Potassium sulfate (K_2SO_4, CAS Reg. No. 7778–80–5) occurs naturally and consists of colorless or white crystals or crystalline powder having a bitter, saline taste. It is prepared by the neutralization of sulfuric acid with potassium hydroxide or potassium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972) as amended by the first supplement (1974),[1] which are incorporated by reference.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.015 percent for nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. Part 186 is amended by adding new § 186.1797 to read as follows:

§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na_2SO_4, CAS Reg. No. 7757–82–6), also known as Glauber's salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation is effective February 25, 1980.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

Dated: January 16, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

Note.—Incorporations by reference were approved by the Director of the Office of the Federal Register on July 10, 1973, and June 27, 1977, and are on file in the Federal Register Library.

[FR Doc. 80–2037 Filed 1–24–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Levamisole Hydrochloride Effervescent Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Cyanamid Agricultural de Puerto Rico, Inc., providing for safe and effective use of levamisole hydrochloride effervescent tablets in swine drinking water for treating nematode infections.

EFFECTIVE DATE: January 25, 1980.

FOR FURTHER INFORMATION CONTACT: Charles E. Haines, Bureau of Veterinary Medicine (HFV–138), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3410.

SUPPLEMENTARY INFORMATION: Cyanamid Agricultural de Puerto Rico, Inc. (CAPRI), Manati, PR 00701, is the sponsor of an NADA (107–085) filed by

American Cyanamid Co. The application provides for use of levamisole hydrochloride effervescent tablets in swine drinking water for treating large roundworm, nodular worm, lungworm, and intestinal threadworm infections. The basic data supporting this use of the drug are contained in CAPRI's NADA 45–513 for levamisole hydrochloride soluble powder. Provisions for use of the powder are codified in 21 CFR 520.1242a. Additional data generated for NADA 107–085 have demonstrated swine acceptability of the tablet-solution and its bioequivalency to the soluble powder-solution. The regulations are amended to provide for use of the new dosage form.

Approval may be granted for a new dosage form without a complete review of the underlying data if the new dosage form does not involve a change in the route of administration, does not require increased dosage, does not introduce variables expected to affect the safety of residues left by the drug, and is demonstrated to be bioequivalent to the approved product. These conditions have been met by CAPRI in this application. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy, issued in the **Federal Register** of December 23, 1977 (42 FR 64367), the approval of this NADA has been treated as would an approval of a Category II supplement and did not require reevaluation of the safety and effectiveness data in related NADA 45–513.

In accordance with the provisions of Part 20 (21 CFR Part 20) promulgated under the Freedom of Information Act (5 U.S.C. 552) and the freedom of information regulations in § 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is available for public examination at the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended by adding new § 520.1242e to read as follows:

§ 520.1242e Levamisole hydrochloride effervescent tablets.

(a) *Specifications.* Each tablet contains 907 milligrams of levamisole hydrochloride.

(b) *Sponsor.* See No. 043781 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount.* The equivalent of 8 milligrams of levamisole hydrochloride per kilogram of body weight, as a single dose.

(2) *Indications for use.* See § 520.1242a(f)(3)(ii).

(3) *Limitations.* Withholding water from pigs before treatment is not necessary. Add one tablet for each 2½ gallons of water; mix thoroughly. Allow 1 gallon of medicated water for each 100 pounds body weight of pigs to be treated. No other source of water should be offered. After pigs have consumed medicated water, resume use of regular water. Pigs maintained under conditions of constant worm exposure may require re-treatment within 4 to 5 weeks. Consult your veterinarian before administering to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Do not administer within 72 hours of slaughter for food.

Effective date. This regulation is effective January 25, 1980.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: January 11, 1980.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 80–2041 Filed 1–24–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Products Co., providing for safe and effective use of a 10-gram-per-pound tylosin premix for making cattle feeds.

EFFECTIVE DATE: January 25, 1980.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV–136), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5247.

SUPPLEMENTARY INFORMATION: Elanco Products Co., a Division of Eli Lilly & Co., 740 South Alabama St., Indianapolis, IN 46206, holds approval for an NADA (12–491) providing for use of a 10-gram-per-pound tylosin (as tylosin phosphate) premix for manufacturing feeds for broiler chickens, chickens, laying hens, replacement hens, and swine. Elanco submitted a supplemental NADA providing for use of the premix in manufacturing beef cattle feed in addition to the preceding uses. This use is already provided for in § 558.625(f)(1)(i) (21 CFR 558.625(f)(1)(i)). The regulation is amended to reflect approval of this supplement.

This approval does not change the approved use of the drug. Consequently, approval of this NADA poses no increased human risk from exposure to residues of the animal drug, nor does it change the conditions of the drug's safe use in the target animal species. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy, issued in the **Federal Register** of December 23, 1977 (42 FR 64367), the approval of this supplemental NADA did not require reevaluation of the safety and effectiveness data in NADA 12–491.

In accordance with the provisions of Part 20 (21 CFR Part 20) promulgated under the Freedom of Information Act (5 U.S.C. 552) and the freedom of information regulations in § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information supporting approval of this application is available for public examination at the office of the Hearing Clerk (HFA–305), Rm. 4–65, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.625 by revising paragraph (b)(1) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(1) To 000986: 10 and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraph (f)(1) (ii) through (vi) of this section.

* * * * *

Effective date. This regulation is effective January 25, 1980.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))